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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

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THE PROCTER & GAMBLE COMPANY
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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,351	JANDACEK ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/23/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,9-12 and 49-53* is/are pending in the application.

4a) Of the above claim(s) *49-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,5-7,9-12 and 49-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The response filed on **8/23/10** has been entered.

2. Applicant's arguments filed 8/23/10 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3, 5-7, 9-12 and 49-53 are pending in this office action. Claims 1, 3, 5-7, 9-12 are examined and claims 49-53 are withdrawn due to the restriction requirement.

5. The objection of claim is withdrawn due to the amendment of the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. (US 6,703,369) in view of Maeder et al. (US 6,730,319) and Park et al. (US 5,750,585, already made of record).

Applicant argues that "De Smidt et al. discloses only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. The current application claims and discloses ethers of fatty alcohols mono-functional alcohols (R-OR'), and not polyols".

"Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form. See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand"

Finally, that "the hydrogels of Park et al. are prepared by introducing a gas into a monomer solution comprising at least one hydrophilic olefin monomer compound. The hydrogels of Park et al. are not formed from an emulsification process using hydrophobic monomers. The compositions of Park et al. are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer. Thus, the compositions of Park et al. and the present invention are not the same"

In response contrary to Applicant's argument de Schmidt specifically teach glyceride esters wherein R is from 12-22 carbon atoms wherein the glyceride ester is chosen from a group of **monoglyceride** (see col. 3, lines 48-65), thus not polyols.

With respect to Maeda, it is not clear what is being argued because no where in the claims is there a recitation of "...solid to liquid form" as asserted by Applicant. When the specification is used as a dictionary, it clearly discloses that the "preferred fatty acid is behenic acid" see page 10, lines 7-10). Therefore if the same compound is used in the prior art as that claimed it must posses the same characteristics because as stated in the MPEP 2112.01 "products of identical chemical composition can not have mutually exclusive properties".

As to the argument that the compositions of Park et al. are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer is not considered because Applicant is arguing what is not claimed.

Finally, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *See In re Keller,* 642 F

2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck &Co.*, 800 F.2d 1091, 231 USPQ (Fed. Cir. 1986).

Thus, Applicant's arguments have been fully considered but they are not persuasive for the reasons given above.

In Summary

The claims are directed to a composition comprising a stiffening agent having a complete melting point of about 37°C or greater, a lipase inhibitor and a non-digestible, non-absorbable, open-celled HIPE foam.

With regards to claim 1 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) or a fatty acid (see abstract and col. 1 lines 50+), R is (12-20) (see col. 3, line 60), with a melting point of 37°C and

(ii) a lipase inhibitor (i.e., orlistat known also known as tetrahydrolipstatin, see col. 1 lines 46+ and col. 3, lines 27-35) wherein the ratio of the stiffening agent is at least 4.5:1 (see col. 4, lines 38-65), the stiffening agent varies between 0.5 and 90% and the lipase inhibitor varies from 1-50% (as required by instant claims 1(a & b), 3, 5-7, 9-11). Intrinsically, one of ordinary skill in the art would routinely adjust the ratios based on the amount of either the lipase inhibitor or the stiffening agent to arrive at the claimed ratios recited in claims 7 and 9-11. For example if the stiffening agent present in an amount of 45% and the lipase inhibitor present is 10%, the ratio therefore is 4.5:1 or 90% of the stiffening agent to 20% of the lipase inhibitor.

However, de Smidt fails to teach the specific stiffening agent as calcium stearate, behenic acid and mixtures thereof as required by instant claim 12, and also fails to teach a non-digestible, non-absorbable, open-celled HIPE foam. Therefore Maeder and Park are added to remedy this deficit.

Maeder et al. teach a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claims 1, 3 and 12.

However Maeder et al. fails to teach a non-digestible, non-absorbable, open-celled HIPE foam.

Park et al. teach a non-digestible, non-absorbable, open-celled HIPE foam compositions and methods of orally administering said forms compositions for the treatment of obesity (see column 3, lines 15-25 and column 15, lines 16-32, as it relates to claim 1).

However, Park fails to teach a lipase inhibitor.

Although de Smidt fails to teach the specific stiffening agent and the non-digestible, non-absorbable, open-celled HIPE foam, it would have been obvious to one having ordinary skill in the art at the time the invention was made to expand the teachings of de Smidt to include a non-digestible, non-absorbable, open-celled HIPE foam in the drug delivery foam compositions disclosed by Park et al. for formulation of a composition for reducing fat absorption or for treating obesity, as taught by de Smidt. One of ordinary skill in the art would have had reasonable expectation of success in the

formulation of the composition for fat absorption and treatment of obesity because Park et al. teach that open-celled foam compositions can be used as oral drug delivery system, in oral dosage forms for reducing fat absorption and treating obesity.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
10/5/10

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628